

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: HARPOLD *et al.*

Serial No. 07/938,154

Filed: November 30, 1992

For: HUMAN NEURONAL NICOTINIC  
ACETYLCHOLINE RECEPTOR  
COMPOSITIONS AND METHODS  
EMPLOYING SAME

Art Unit: 1812

Examiner: Ulm, J.

I hereby certify that this paper and the attached  
papers are being deposited with the United  
States Postal Service as first class mail in an  
envelope addressed to:

Assistant Commissioner for Patents  
Washington, D.C. 20231, on this date.

5/09/97

Date

Sherie E. Stewart

**SUBMISSION OF INFORMATION UNDER 37 C.F.R. §1.56  
AND SUBMISSION OF A DECLARATION UNDER 37 C.F.R. §1.132**

Assistant Commissioner for Patents  
Washington, D.C. 20231

Dear Sir:

In accord with the continuing duty of disclosure, A DECLARATION by Edwin C. Johnson, attached hereto, with a publication Chavez-Noriega *et al.*, entitled "Pharmacological Characterization of Recombinant Human Neuronal Nicotinic Acetylcholine Receptors  $\alpha 2\beta 2$ ,  $\alpha 2\beta 4$ ,  $\alpha 3\beta 2$ ,  $\alpha 3\beta 4$ ,  $\alpha 4\beta 2$ ,  $\alpha 4\beta 4$  and  $\alpha 7$  Expressed in *Xenopus* Oocytes" (*J. Pharmacol. Exp. Ther.*, 280:346-356 (1997)) is provided. Entry of the DECLARATION and accompanying paper into the file history of the above-captioned application is respectfully requested. The original of the signed DECLARATION will be mailed under separate cover.

The Commissioner is hereby authorized to charge any fee, including any submitted herewith if the attached check(s) is in the wrong amount or otherwise improper or missing, that may be due in connection with this and the attached papers, or with this application during its entire pendency to or to credit any overpayment to Deposit Account No. 02-4070.

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In accordance with the duty of disclosure imposed by 37 C.F.R. §1.56 to inform the Patent Office of all information that may be material to the examination of the subject application, a copy of Chavez-Noreiga *et al.* and an accompanying DECLARATION of Edwin C. Johnson, who submitted a DECLARATION under 37 C.F.R. §1.132 in connection with this application is provided. The paper provides a pharmacological characterization of various human recombinant nicotinic acetylcholine receptor subunits (nAChR), and, as noted in the attached DECLARATION, a qualitative comparison of such subunits with human subunits. As stated in the DECLARATION, the results in the paper support the conclusion in the prior DECLARATION that there are unexpected differences between rat and human neuronal nicotinic acetylcholine receptors. The previous DECLARATION provides a side-by-side comparison of rat and human subunits; whereas, the paper discusses qualitative differences gleaned from the literature regarding rat subunits. Also, the data in the DECLARATION presents results obtained at a selected concentration of agonists. The concentration was selected to be such that differences would not be masked by desensitization of receptors that occurs at higher concentrations.

Although this information is made known to the Patent and Trademark Office in compliance with the duty of disclosure, such disclosure is not to be construed as an admission by that any of this information could be the basis for a rejection of any of the claims of the above-captioned application. The filing Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 C.F.R. §1.56(b) exists.

The following related, co-pending commonly owned applications:

<u>U.S.S.N.</u>	<u>Inventor</u>	<u>Filing date</u>
08/484,722	Elliott <i>et al.</i>	June 7, 1995
08/467,574	Elliott <i>et al.</i>	June 5, 1995
08/466,589	Elliott <i>et al.</i>	June 5, 1995
08/487,596	Elliott <i>et al.</i>	June 7, 1995
08/496,855	Elliott <i>et al.</i>	June 20, 1995

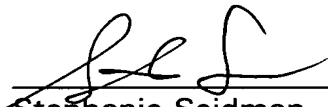
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are also noted. A publication Elliott et al. (1996) J. Mol. Neurosci. 7:217-228, which discloses subject matter in the copending applications, is also attached hereto. This publication also demonstrates that despite sequence similarities there are unexpected species differences in the properties of neuronal nicotinic acetylcholine receptors.

Applicant respectfully requests that the Examiner review the foregoing information make if of record in the file history of the above-captioned application.

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Respectfully submitted,  
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